

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Shenzhen Dymind Biotechnology  
Co., Ltd.  
10th Floor  
Building B, High-tech Park, Guangqiao Road  
Tianliao Community, Yutang Street  
Guangming District  
518107 Shenzhen  
P.R. China**

has established and applies a quality management system for medical devices  
for the following scope:

**(see attachment for scope and sites included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-08-05  
Certificate Registration No.: SX 60150855 0001  
An audit was performed. Report No.: 17051246 014  
This Certificate is valid until: 2023-08-04

Certification Body



Date 2020-08-05

Dipl.-Ing. W. Hsu



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60150855 0001  
**Report No.:** 17051246 014

**Organization:** Shenzhen Dymind Biotechnology  
Co., Ltd.  
10th Floor  
Building B, High-tech Park, Guangqiao Road  
Tianliao Community, Yutang Street  
Guangming District  
518107 Shenzhen  
P.R. China

**Scope:**

Design and Development, Manufacture and Distribution of in-vitro diagnostic test kits, in-vitro diagnostic reagents, calibrators and controls and in-vitro diagnostic analysers used in detection of Specific Proteins, Individual and Specified Hormones / Proteins, Inflammatory Diseases Markers, Cardiac Markers, Immune Status, and the analysis of Haematology.

Sites included:

Shenzhen Dymind Biotechnology Co., Ltd.  
10th Floor, Building B, High-tech Park, Guangqiao Road,  
Tianliao Community, Yutang Street, Guangming District,  
518107 Shenzhen, P.R.China

License Holder Only.

**Certification Body**



**Date: 2020-08-05**

  
**Dipl.-Ing. W. Hsu**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

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Certificate**

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Co., Ltd.  
10th Floor  
Building B, High-tech Park, Guangqiao Road  
Tianliao Community, Yutang Street  
Guangming District  
518107 Shenzhen  
P.R. China

**Scope:**

Sites included:

Shenzhen Dymind Biotechnology Co., Ltd.  
2/F, Nanfeng Building B, Nanshan Yungu Innovation  
Industrial Park, No.4093, Liuxian Blvd, Taoyuan Street,  
Nanshan District, Shenzhen 518055, P.R. China

Design and Development, and Distribution of in-vitro  
diagnostic test kits, in-vitro diagnostic reagents,  
calibrators and controls and in-vitro diagnostic analysers  
used in detection of Specific Proteins, Individual and  
Specified Hormones / Proteins, Inflammatory Diseases  
Markers, Cardiac Markers, Immune Status, and the analysis  
of Haematology.

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**LGA Products GmbH**  
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**Organization:** Shenzhen Dymind Biotechnology  
Co., Ltd.  
10th Floor  
Building B, High-tech Park, Guangqiao Road  
Tianliao Community, Yutang Street  
Guangming District  
518107 Shenzhen  
P.R. China

**Scope:**

Sites included:

Shenzhen Dymind Biotechnology Co., Ltd.  
Floor 1 & 4, Area A, Building B, Yeming mold industrial  
park, Genyu Road, Tianliao Community, Yutang subdistrict  
office, Guangming New District, Shenzhen 518132, P.R.China

Manufacture of in-vitro diagnostic test kits, in-vitro  
diagnostic reagents, calibrators and controls used in  
detection of Specific Proteins, Individual and Specified  
Hormones / Proteins, Inflammatory Diseases Markers, Cardiac  
Markers, Immune Status, and the analysis of Haematology.

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10th Floor  
Building B, High-tech Park, Guangqiao Road  
Tianliao Community, Yutang Street  
Guangming District  
518107 Shenzhen  
P.R. China

**Scope:**

Sites included:

Shenzhen Dymind Biotechnology Co., Ltd.  
7th-10th Floor, Room 1101, 11th Floor, 12th Floor, Building  
B, High-tech Park, Guangqiao Road, Tianliao Community,  
Yutang Street, Guangming District,  
Shenzhen 518107, P.R. China

Design and Development, and Distribution of in-vitro  
diagnostic test kits, in-vitro diagnostic reagents,  
calibrators and controls and in-vitro diagnostic analysers  
used in detection of Specific Proteins, Individual and  
Specified Hormones / Proteins, Inflammatory Diseases  
Markers, Cardiac Markers, Immune Status, and the analysis  
of Haematology

Manufacture of in-vitro diagnostic analysers used in  
detection of Specific Proteins, Individual and Specified  
Hormones / Proteins, Inflammatory Diseases Markers,  
Cardiac Markers, Immune Status, and the analysis of  
Haematology

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